

01/03/02



*Preempt*  
PATENT

Customer Number 22,852  
Attorney Docket No. 04995-0044-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Prior Application Art Unit: 1645 Prior Application Examiner: Jennifer Graser

SIR: This is a request for filing a

☐ Continuation ☐ Continuation-in-Part ☒ Divisional Application under 37 C.F.R. § 1.53(b) of pending prior application Serial No. 09/281,274 filed March 30, 1999 of Anthony MAURELLI et al. for

METHODS OF IDENTIFYING BACTERIAL GENES THAT ARE INCOMPATIBLE WITH BACTERIAL PATHOGENICITY, AND THE USE OF SUCH GENES, SUCH AS CADA, TO REDUCE PATHOGENICITY IN A BACTERIA OR TO COMBAT PATHOGENIC BACTERIAL INFECTIONS

1. ☒ Enclosed is a complete copy of the prior application including the oath or Declaration and drawings, if any, as originally filed. I hereby verify that the attached papers are a true copy of prior application Serial No. 09/281,274 as originally filed on March 30, 1999, which is incorporated herein by reference.
2. ☐ Enclosed is a substitute specification under 37 C.F.R. § 1.125.
3. ☐ Enclosed is a Request for Non-Publication of Application and Certification Under 35 U.S.C. § 122(b)(2)(B)(i).
- ✓ 4. ☒ Cancel Claims 9-41.
5. ☐ A Preliminary Amendment is enclosed.
6. ☒ Amend the specification by inserting before the first line, the following new paragraph:

01  
This is a division of application Serial No. 09/281,274, filed March 30, 1999, and claims the benefit of U.S. provisional application No. 60/080,202, filed March 31, 1998, both of which are incorporated herein by reference.

7. ☐ New formal drawings are enclosed.

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## GOVERNMENT INTEREST

The invention described herein may be manufactured, licensed, and used for governmental purposes without payment of royalties to us thereon.

### CROSS-REFERENCE TO RELATED APPLICATION

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a1 > This application is related to Provisional Patent Application Serial No. 60/080,202, filed on March 31, 1998, which application is incorporated herein by reference.

### FIELD OF THE INVENTION

2003413-010302  
This invention relates to the inventive procedure for identifying "anti-virulence" genes which are incompatible with virulence. This inventive principle is illustrated by the identification of the anti-virulence gene *cadA*. A further aspect of this invention is derived from this identification, because the gene products of these anti-virulence genes, or the compounds generated enzymatically by these gene products, are useful as pharmaceuticals. As exemplified by the compound generated by the product of the *cadA* gene (lysine decarboxylase), the invention relates to the use as a pharmaceutical of the diaminoalkanes and polyaminoalkanes in the treatment and prevention of pathogenic bacterial infections. Of particular use is cadaverine (1,5-diaminopentane).

As further support, and as a further embodiment, is the identification of *nadA* and *nadB* as anti-virulence genes, and the pharmaceutical use of the corresponding enzymatically generated compound, quinolinate.

The identification of a gene related to non-pathogenicity also permits the modification of pathogenic bacteria with the gene to thereby diminish pathogenicity. Thus, the invention includes modified pathogenic bacteria, including DNA constructs, vectors, plasmids, and organisms. This